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retaining the polymeric sheet or tube on the stent structural member such that the polymeric sheet or tube fills gaps in the roughened or patterned outer surface to form a smooth exterior surface.

Please add new claim 22 as indicated below:

22. (New) A stent, comprising:

a structural support having an outer surface that includes a pattern of raised squares; and

a polymeric film or sheet or tube that overlays the structural support wherein the polymeric film or sheet or tube is retained to the structural support by the raised squares.

REMARKS

Applicant is grateful for the interview with the Examiner conducted on July 23, 2002. Applicant has attempted to address the issues raised by the Examiner at the interview in this amendment.

Applicant requests reconsideration of the application in view of the preceding amendments and the following remarks. Claims 1-4 and 12-15 have been amended. New claim 22 has been added. Claims 1-22 are pending. Claims 1, 12, 15, 16, 19 and 22 are independent claims.

Amendments to the specification and drawings were made to correct typographical errors. Support for the amendments to the claims is found in the specification and drawings as filed. No new matter has been added in making the amendments herein.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

DRAWING AMENDMENTS

Three sheets of drawings containing FIGS. 4, 5, 5A, 5B, 7, 8A, 8B, 9A, 9B, 10, 10A and 10B showing proposed corrections in red ink are enclosed for the Examiner's review. Upon approval of the proposed drawing corrections, Applicant proposes to file formal corrected drawings implementing the proposed drawing corrections. Specifically, the drawings have been amended to add and clarify reference numerals. No new matter is added.

SPECIFICATION AMENDMENTS

All amendments to the specification have been made to correct typographical errors and do not add new matter. In particular, the amendments were made to provide a clearer description of the embodiment of the invention shown in FIG. 7.

CLAIM OBJECTIONS

The Examiner objected to claims 14 and 15 because of informalities. Specifically, the Examiner indicated that both occurrences of "inches" in claim 14 should be "inch" and "roughing" in claim 15 should be "roughening." Applicant has amended the claims as suggested by the Examiner.

35 U.S.C. §102(b) REJECTIONS

The Examiner rejected claims 1-3, 6, and 8-13 under 35 U.S.C. § 102(b) as being anticipated by Dayton, U.S. Patent No. 5,778,075. Applicant respectfully disagrees with the Examiner's reading of the cited reference and traverses these rejections.

Applicant respectfully submits that Dayton does not teach or suggest a polymeric film or sheet or tube that is retained to the structural support by the roughened or patterned outer surface, as recited in claims 1 and 12. Dayton teaches tabs 19, 20 which engage holes 17 in the stent 11, thereby preventing the stent from recoiling to its smaller delivery diameter. (See Dayton at col. 5, ll. 59-64, col. 6, ll. 4-17 and 32-38, and FIGS. 2-4 and 8-10). Furthermore, although Dayton teaches a stent with a polymer forming the exterior surface, the polymer is a coating which is formed when the stent is “dip[ped]” or “submerge[d]” in a solution or when a solution is “sprayed” or “pour[ed]” on the stent. (See Dayton col. 6, ll. 54-56 and col. 7, ll. 34-55). Moreover, the coating of Dayton is not retained by the tabs. If the coating of Dayton were retained by the tabs, it would not be true that the tabs are not needed when the stent has an outward biasing tendency. (See Dayton col. 6, ll. 44-45). Applicant respectfully submits that the tabs taught by Dayton are solely for the purpose of preventing the expanded stent from recoiling and the polymer is not retained by the tabs.

Although Applicant disagrees with the Examiner’s reading of Dayton, claims 1 and 12 have been amended to further differentiate between the present invention and the teachings of the Dayton reference. Claims 1 and 12 have been amended to recite that the polymeric film or sheet or tube fills in gaps in the roughened or patterned outer surface and that the exterior surface of the stent is substantially smooth. This feature is best seen in the cross-sectional views of FIGS. 5A, 5B, 8A, 8B, 10A, and 10B. The exterior surface of the stent is indicated, respectively, by reference numeral 24 in FIGS. 5A and 5B, reference numeral 49 in FIGS. 8A and 8B, and reference numeral 62 in FIGS. 10A and 10B. The roughened or patterned surface is indicated by reference numeral 20. It is respectfully submitted that amended claims 1 and 12 are patentable over Dayton, which neither teaches nor suggests a film that fills in gaps in the roughened or patterned outer surface or a stent with a smooth exterior surface. As can best be seen in the cross-sectional views at FIGS. 4 and 10, the tabs 19, 20 of Dayton extend beyond the outer surface of the stent and, therefore, the polymer does not fill in gaps created by the tabs in the surface of the stent. Furthermore, Dayton teaches tabs that engage the side walls of the anatomy

where the stent is deployed -- the stent obviously not having a smooth exterior surface. (See Dayton col. 6, ll. 36-39).

For the reasons cited above, Applicant respectfully asserts that amended independent claims 1 and 12 are allowable over Dayton. Applicant further respectfully asserts that claims 2, 3, 6, and 8-11, which depend upon claim 1, and claim 13, which depends upon claim 12, are also allowable over Dayton.

The Examiner rejected claim 15 under 35 U.S.C. § 102(b) as being anticipated by Tartaglia et al., U.S. Patent No. 5,637,113. Applicant respectfully traverses this rejection.

The Examiner interprets the “patterning of slotted openings” in the stent of the Tartaglia et al. reference as a method of adhering the polymeric sheet to the stent structural member. (See Office action item 4 on page 3). Applicant has amended claim 15 to recite that the outer surface of the stent structural member has a raised textured design, the support for this limitation found in the specification. Applicant respectfully submits that the “patterning of slotted openings” of Tartaglia et al. is not a raised textured design. This is most notable by comparing FIGS. 1 and 2 of the Tartaglia et al. reference with FIGS. 5A, 5B, 8A, 8B, 10A, and 10B of the specification. FIGS. 1 and 2 of Tartaglia et al. show the cross-section of a stent 20 having a structural member 22 whose exterior surface is relatively smooth. On the other hand, FIGS. 5A, 5B, 8A, 8B, 10A, and 10B of the specification show the cross-section of stents having a roughened or patterned surface 20 that is “raised” and “textured.” Applicant respectfully asserts that because Tartaglia et al. neither teaches nor suggests roughening or patterning the outer surface of the stent structural member with a raised textured design, amended claim 15 of the present invention is allowable.

The Examiner rejected claims 16-21 under 35 U.S.C. § 102(b) as being anticipated by Yan, U.S. Patent No. 5,843,172. Applicant respectfully disagrees with the Examiner’s reading of the cited reference and traverses this rejection.

To support his contention that Yan teaches a stent having a structural member with a “roughened or texturized surface” and a “polymeric sleeve or sheet,” the Examiner identifies portions of the Yan reference which teach the creation of porous cavities in a metal stent by

sintering, loading the space between the lattice of the particles with a therapeutic agent, and coating the sintered metal with a polymeric material. (See Office action item 5 at page 3). However, it is respectfully noted that the Examiner does **not** contend that Yan teaches the polymeric sleeve or sheet is retained to the structural support by the roughened or texturized surface, as recited in claims 16 and 19. It is respectfully submitted that Yan teaches using a sintered metal stent in order to load drugs into the pores of the sintered metal, not as a means of retaining a polymeric sleeve or sheet to the stent. (See Yan at col. 1, ln. 62 to col. 2, ln. 14, col. 7, ll. 17-29 and FIG. 7).

Applicant respectfully asserts that because Yan does not teach that the polymeric sleeve or sheet is retained to the structural support by the roughened or texturized surface, claims 16 and 19 are allowable thereover. Applicant further respectfully asserts that claims 17-18, which depend upon claim 16, and claims 20-21, which depend upon claim 19, are also allowable over Yan.

35 U.S.C. §103(a) REJECTIONS

The Examiner rejected claims 5 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Dayton in view of Williams, U.S. Patent No. 5,423,885. Applicant respectfully traverses these rejections.

As noted above, Dayton does not teach or suggest a polymeric film or sheet or tube that is retained to the structural support by the roughened or patterned outer surface, or that the polymeric film or sheet or tube fills in gaps in the roughened or patterned outer surface such that the exterior surface of the stent is smooth, as recited in amended claim 1 of the present invention. Applicant further respectfully submits that Williams also does not teach or suggest the aforementioned limitations recited in claim 1. Therefore, Applicant respectfully asserts that claim 1 is patentable over both Dayton and Williams. Applicant further respectfully asserts that claims 5 and 7, which depend upon claim 1, are also patentable over the cited references.

The Examiner rejected claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Dayton as a matter of design choice. As noted above, claim 12 is allowable over Dayton since Dayton does not teach or suggest a polymeric film or sheet or tube that is retained to the structural support by the roughened or patterned outer surface nor that the polymeric film or sheet or tube fills in gaps in the roughened or patterned outer surface such that the exterior surface of the stent is smooth. Applicant respectfully asserts that claim 14, which depends upon claim 12, is also patentable over Dayton. Lastly, Applicant disagrees that the raised triangles are a matter of design choice.

ALLOWABLE SUBJECT MATTER

Applicant is grateful for the Examiner's suggestion of allowable subject matter based on claim 4. Applicant has rewritten claim 4 as new independent claim 22 to include all the limitations of base claim 1 and any intervening claims as suggested by the Examiner. Applicant therefore believes that new independent claim 22 is in condition for allowance.

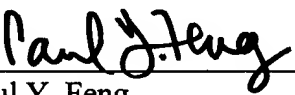
CONCLUSION

Applicant has attempted to respond to each and every objection and rejection set forth in the outstanding Office action. In view of the above amendments and remarks, Applicant respectfully requests that the application be reconsidered, the claims allowed and the application passed to issue.

Applicant kindly asks that the Examiner update the attorney docket number to:
ACS- 59046 (1873P).

Respectfully submitted,

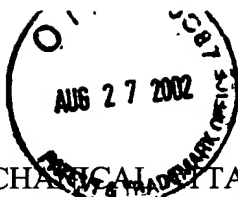
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

The paragraph beginning on page 7, line 3 has been amended as indicated:

In another embodiment of the present invention, illustrated generally in Fig. 7, the stent is drug laden so that the stent comprises a stent metal structural member 42 and a planar sheet or film of polymeric material 44. The film of polymeric material 44 has a first end 46 [forming] of a first layer 47 of polymeric material and a second [layer] end 48 [overlapping the first end forming] of a second layer 49 overlapping the first end 46 and attached to the first layer 47 of the polymeric film 44[, preferably the textured or roughened surface]. Attachment of the first layer 47 of the polymeric film is accomplished by the textured or roughened surface of the present invention on the stent structural member 42.

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IN THE CLAIMS

The following claims have been amended as indicated:

1. (Amended) A stent, comprising:
a structural support comprising an outer surface that is roughened or patterned; and
a polymeric film or sheet or tube that overlays the structural support wherein the polymeric film or sheet or tube is retained to the structural support by the roughened or patterned outer surface and fills in gaps in the roughened or patterned outer surface such that the exterior surface of the stent is smooth.

2. (Amended) The stent of claim 1 wherein the roughened or patterned outer surface [has a pattern of] comprises raised triangles.

3. (Amended) The stent of claim 1 wherein the roughened or patterned outer surface [has a pattern of] comprises spikes.

4. (Amended) The stent of claim 1 wherein the roughened or patterned outer surface [has a pattern of] comprises raised squares.

12. (Amended) A [retaining] system for retaining a polymeric film or sheet or tube on a stent, comprising a roughened or a patterned outer surface on the stent wherein the polymeric film or sheet or tube fills in gaps in the roughened or patterned outer surface such that the exterior of the stent is smooth.

13. (Amended) The retaining system of claim 12 wherein the roughened or patterned surface comprises one or more of raised squares or triangles or spikes.

14. (Amended) The retaining system of claim 13 wherein the [raised] squares or triangles or spikes are raised from about 0.001 inch[es] to 0.005 inch[es].

15. (Amended) A method for adhering a polymeric sheet to a stent structural member, comprising:

providing a stent structural member with an outer surface;

providing a polymeric sheet or tube;

5 [roughing] roughening or patterning the outer surface of the stent structural member with a raised textured design; and

retaining the polymeric sheet or tube on the stent structural member such that the polymeric sheet or tube fills gaps in the roughened or patterned outer surface to form a smooth exterior surface.